Public Health Safeguard under the Provision of TRIPS: India's Legal Response

A Synopsis

Submitted in

Partial fulfillment for the degree
Of
Doctor of Philosophy

(Law)

Supervised by
JV'n Prof. (Dr.)R.K.Patni

Submitted by
JV'n Mr.Ashutosh kr.Srivastava

Department of Law & Governance,
Faculty of Law
Jayoti Vidyapeeth Women's University, Jaipur (Rajasthan)
March, 2013

INTRODUCTION

The word patent originated from the Latin word ‘Patene’ which means ‘to open’ the concept of patent system is very old one. Word patent, at least in some of the European languages, is used in two senses. One of them is the document that is called “Patent” or “letter of Patent" the other is content of protection that a patent confers. If a person makes what he thinks is an invention he or if he works for an entity , that entity can ask the government , by filling an application with the patent office to give him a document in which it is stated what the invention is and that he is the owner of patent. This document, issued by a government authority is called a patent or a patent for invention. Therefore the patent is a license given to an inventor to make exclusive use of his invention .The patent can be correctly defined as exclusive right to use and exercise an invention granted to a person for a limited period in consideration of the disclosure of the invention.

AREA OF CONCERN

Drug patenting is the negative right over the drugs i.e. no one else can use the rights of manufacturing of that drug, in rest of the world. By the provision of statute these negative rights squeeze for 20 years but most of the Inventor /Patent holder hold such rights over the drug for next 20 years by slight change in Drug component therefore they enjoys this patent perpetually, and they hold such high price on life saving drugs.

Perpetual patent holder regulate drugs price & quantity of drugs in open market, by this way they regulate Drug market and enhance their reputation in open world. Sometimes they work as a pressure group on government’s drug making policies. Government becomes unable to hold administered price on life saving drugs & some other curing general drugs.

Intellectual property right is the right given to the intellectual creativity of an individual .The inventor will always want to recoup his investment .unless there is an opportunity to recoup investment, there will be no incentive to invest in creative effort.

In every intellectual property right two interests are involved, public and privet .The privet wants access to the maximum economic advantages out of his invention while the public want access to the maximum possible inventions at the cheapest price.

The intellectual property right is an attempt to balance the conflicting interests of public on one hand and the privet on other.

Patents give the holder an exclusive right to use and license use of an invention for a certain period. It prevents those who do not have right holder's license from making, using, selling, or importing the patented products. The right granted by patent is not a positive right, but a negative right which enables the patent holder to prevent a third party from making or using the product. Patented pharmaceuticals have to go through rigorous testing and approval before they can be put on the market.

The effect of the grant of patent are that the patented invention may not be exploited in the country by persons other then the owner of the patent unless the owner agrees to such exploitation. Right to take action against any person exploiting the patented invention in the country without his consent permits him to derive the benefits of the invention. It is reward for his intellectual effort and compensation for the expenses incurred in research and development of the invention. A patent will be granted only if the disclosure of the invention in the patent application is enabling1. A patent specification is address to those likely to have a practical interest in the subject matter of the invention. Such persons are those with practical knowledge and experience of the third kind of work in which invention is intended to be used. If a patentee describes a new non obvious compound which has a beneficial effect and describes a way by which it can be made then he is entitled to a patent for the compound.

[1] Patent Act 1970,S 2(J)reads "Invention means a new product or process involving an inventive step and capable of industrial application"

Justice kitchin of England and Wales High Court[2] has recently rendered a judgment in which the patent was revoked on the ground that the claim was too broad when the patent claimed not only the novel way of making the more active enantiomer (pair of compounds (crystals or molecules) that are mirror images on each other but are not identical) of citalopram, but effectively all way of making it.

The court concludes that the inventive step taken by the inventor of the patent was not deciding to separate the enantiomer of citalopram but finding a way it could be done. The first person to find a way of achieving an obviously desirable goal is not permitted to monopolies every other way of doing so.

Even if an invention satisfies these statutory criteria, the invention will not be entitle to protection if it falls within the category of non-patentable subject matter[3]

Patent system offers a standard level of protection generating the resources required to finance R & D and to protect investments. Patent right help inventor to recoup his investment and are tool to technical progress.

Despite the significant scientific and technological developments**,** there continue to exist unacceptable inequalities in the health status of people as between developed and developing countries as well as within developing countries. prior to the trade related aspects of intellectual property Rights (TRIPS) Agreement**,** intellectual property rights was largely an unregulated area ,minimally protected and administered by world intellectual property organization and also Paris convention. Pre-Uruguay round intellectual property regimes were largely left to national discretion whereby there was divergence in laws between the developed and developing country.

[2] Generics (UK)Ltd vs .H.Lundbeck ,(2007)EWHC 1040 (Pat)
[3] Patent Act 1970 sce.3

efforts to make medical technology work better for developing countries and for poor people has focused on the impact on the expansion of patent protection to pharmaceutical product and process under the TRIPS.

TRIPS are an international agreement and establish minimum standards that require member countries to prove some intellectual property protection in domestic law. the main rule relating to patentability under the TRIPS agreement is that patents shall be available for any invention ,whether a product or process**,** in all fields of technology**,** provided the inventions meet the criteria for the patentability i.e. namely**,** novelty inventive step and industrial applicability. In addition members are required to make grant of a patent dependent on adequate disclosure of the invention and may require information on the best mode for carrying it out.[4] Enabling disclosure is an important element as it makes important technical information publicly available .This can be utilized by other advancing technology in the area. It also ensures that, after the expiry of the patent term, the invention falls into the public domain. Without the technical information behind an invention, after the expiry of the patent protection, others will not be able to exploit it .patent protection has to last at least 20 years from the date the patent application filed.[5]

One important challenge to the TRIPS Agreement relates to the high costs of essential medicines and related products due to mandatory requirement under the TRIPS Agreement for product patent protection for medicines .Before the adoption of TRIPS Agreement most of the countries did not grant patent s for medicines so as to keep the cost low and affordable and to censure their ready availability to their populations at all times.

[4] TRIPS Agreement Art.29
[5] TRIPS Agreement Art 33

The clear concern of the TRIPS Agreement vis –a-vis the pharmaceutical sector is that the introduction of product patents may imply significant social cost due to the higher prices charged for medicaments. The price of medicines is a key factor in determining how accessible they are to poor people. Research and development is very expensive**,** for each drug successfully brought into the market**,** pharmaceutical companies would have expended billions on research and development including the thousands of molecules that might have gone waste in developing the drug.

But ultimate object of every medical research ,or health business is to uplift the health status of general people**,** as it expressed in directive principles under article 39 (a) to (f)[6] that economic system does not result in concentration of wealth it should be distributed among the all citizens because it is liability of state to maintain health status of its citizens and it expended in article 21 of Indian constitution by Supreme court of India in **Parmanand katara vs union of India (AIR 1989 SC 2039)**,as right to health[7]. According to above mentioned constitutional liabilities toward its citizen parliament made Indian patent act 1970 as a buffer act in-between the rights of patentee and Indian society.

[6] Article 39 sub claus (a to f)of Constitution of India
[7] In this case supreme court decided right to health as fundamental right

Two Opinions for existing controversies

“Affluent societies are spending vast sums of money understandably on the search for new products and processes to alleviate suffering and to prolong life. In the process, drug manufactures have become a powerful industry. My idea of a better- ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death.”

Mrs. Indira Gandhi, (World Health Conference , 1982)

"If people don’t get a fair return in innovation, they won’t invest in finding new cures for disease — this will be disastrous for patients”

Ranjit Shahani, Vice-Chairman & Managing Director, Novartis India Limited

Objectives

- To analyze the effect of TRIPs provision on drugs patent and public health in Indian context
- To find out public health safeguards under TRIPs and in Indian patent regime.
- To analyze the effect specially on Cancer patients
- To Identify & Analyze the different kinds of problems that are created by high prices of life saving Drugs due to the perpetuity rights of patentee
- Whether -Drug patenting is distribution of health or concentration of wealth

Review of Literature

Ellen F. M.'t Hoen The : in 2003 in his book **"***TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond" he stated that - The* reasons for the lack of access to essential medicines are manifold, but in many cases the high prices of drugs are a barrier to needed treatments. Prohibitive drug prices are often the result of strong intellectual property protection. Governments in developing countries that attempt to bring the price of

medicines down have come under pressure from industrialized countries and the multinational pharmaceutical industry. The World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) sets out the minimum standards for the protection of intellectual property, including patents for pharmaceuticals. While TRIPS does offer safeguards to remedy negative effects of patent protection or patent abuse, in practice it is unclear whether and how countries can make use of these safeguards when patents increasingly present barriers to medicine access.

Public health advocates welcomed the Doha Declaration as an important achievement because it gave primacy to public health over private intellectual property, and clarified WTO Members' rights to use TRIPS safeguards. But the Doha Declaration did not solve all of the problems associated with intellectual property protection and public health. The recent failure at the WTO to resolve the outstanding issue to ensure production and export of generic medicines to countries that do not produce may even indicate that the optimism felt at Doha was premature.

Carlos María Correa: In 2007 in his book "Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement" he stated that-"The TRIPS Agreement is the most comprehensive and influential international treaty on intellectual property rights. It brings

intellectual property rules into the framework of the World Trade Organization, obliging all WTO Member States to meet minimum standards of intellectual property protection and enforcement. This has required massive changes in some national laws, particularly in developing countries. This volume provides a detailed legal analysis of the provisions of the TRIPS Agreement, as well as considering their economic implications in different legal and socio-economic contexts." "This book examines the obligations imposed on WTO Members in different fields of intellectual property, and thoroughly explores the flexibilities that they enjoy in implementing the Agreement."

Medury Bhaskara Rao, Manjula Guruin, 2003 in his book "Understanding TRIPs: managing knowledge in developing countries" Intellectual Property Rights (IPRs) are those that deal with copyrights, patents and trademarks. The controversial TRIPS (Trade Related Intellectual Property Rights) agreement that was a result of the Uruguay Round negotiations, aims to strengthen IPRs by checking piracy, illegal imports, and other violations. In addition, it also seeks to strengthen the enforcement provisions by setting up a dispute settlement procedure. While there are similar laws, for example, in the areas of copyright and trademark protection in both the developed and the developing countries of the world, the differences arise on patent protection and enforcement of these rights.

This lucid book comprehensively explains the TRIPS agreement and its effect on the developing countries. In this exhaustive volume consisting of twelve chapters, the provisions of the agreement are examined article wise. Also, it traces the negotiating history and critically examines the case law of the agreement. The author has also discussed and analysed the Indian law on the subject in detail, anti competitive practices, industrial design, and the protection of undisclosed information among other topics in the book. The book will be an invaluable resource

to professionals in general and strategic management, business leaders, lawyers, and students of international business, law, finance and management. It will also be useful to policy analysts and diplomats.

Martin A. Voet in 2011 in his book “The Generic Challenge: Understanding Patents, FDA and Pharmaceutical life cycle management”.

Rexford E. Santerre, Stephen P. Neunin 2009 in his book “Health Economics: Theories, Insights, and Industry Studies” stated that With the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), the effective life of a new drug patent is extended by a maximum of 5 years, but not beyond 14 years of effective life.

Jakkrit kuanpoth, in 2010 in his book **“**Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges in future**”** state that it is an erudite and constructive contribution to the debate on patents and public health. The book s focus on India and Thailand, both of which have sought actively to balance patent rights with public health goals, provides some valuable findings that should lead to more sensitive intellectual property policymaking in the developing and developed nations .

Dean Baker in 2011 in “Why pharma's patents are a drug on the market” stated that Drugs are cheap. There are few drugs that would sell for more than $5-$10 a prescription in a free market. However, many drugs in the United States sell for hundreds of dollars per prescription and, sometimes, several thousand dollars per prescription. There is a simple reason for this fact: government-granted patent monopolies.

The government gives patent monopolies to provide an incentive for drug companies to carry through research. This is an incredibly backward and inefficient way to pay for research. It leaves us paying huge amounts of money for cheap drugs. It also often leads to bad medicine.

We can do better – and Senator Bernie Sanders has proposed a way. He has introduced a bill to create a prize fund that would buy up patents, so that drugs could then be sold at a free market price. Sanders's bill would appropriate 0.55% of GDP (about $80bn a year, with the economy's current size) for buying up patents, which would then be placed in the public domain so that any manufacturer could use them at no cost.

This money would come from a tax on public and private insurers. The savings from lower-cost drugs would immediately repay more than 100% of the tax.

The country is projected to spend almost $300bn a year on prescription drugs this year. Prices would fall to roughly one-tenth this amount in the absence of patent monopolies, leading to savings of more than $250bn. The savings on lower drug prices should easily exceed the size of the tax, leaving a substantial net reduction in costs to the government and private insurers.

The Sanders prize fund bill would go far towards eliminating the problems that pervade the drug industry. First, it would end the nonsense around getting insurers or the government to pay for drugs. If drugs cost $5-$10 per prescription, there would be no big issues about who pays for drugs. This would eliminate the need for the paperwork and the bureaucracy that the insurance industry has created to contain its drug payments.

We would also end the phony moral dilemmas we create for ourselves with drug patents. Should Medicare pay $100,000 a year for a drug to treat a rare cancer in an otherwise healthy 80 year

old? This dilemma becomes a quick no-brainer when the drug is available for $200 a year in the free market with no patent protection.

The Sanders prize fund could also put an end to many of the deceptive marketing practices that the industry now employs to push their drugs, overstating the benefits of their drugs and concealing potentially harmful side-effects. It is rare that a month goes by when there is not a scandal along these lines. If the drug companies no longer stood to gain billions in profits from such deceptive marketing, they wouldn't do it. It would also likely reduce much of the waste in the current research process. Drug companies often spend large sums developing copycat drugs that are of little medical value, but can allow them to get a portion of a competitor's patent rents.

The Sanders prize fund is not the only possible alternative to patents for supporting research on prescription drugs. We could also go the route of direct, upfront government funding where the government would contract for the research in advance. We already spend more than $30bn a year on such research through the National Institutes of Health. This is widely viewed by health experts as money very well spent.

It would be possible to ramp up this funding by a factor of two or three with the intent of replacing patent supported research. This direct funding would have the advantage that all results would be fully available to researchers and the general public, since that would be a condition of the funding. Representative Dennis Kucinich introduced a bill along these lines was introduced a few years ago.

At this point, we don't have to decide on the best alternative to patent-supported research for prescription drugs; what we have to do is to get the debate started. The Centres for Medicare and

Medicaid Research project that we will spend almost $4tn on prescription drugs over the next decade. This is almost $10,000 for every man, woman and child in the country. It's long past time that we did some serious thinking to ensure that we are getting better value for this money. The Sanders prize fund bill is an important step in this direction.

Wieland Wagner in 2012 in his book ”A License to Steal: India Skirts Patent Laws to Help Companies and Poor” state that Two uniformed attendants in turbans push open the large wooden door to Courtroom No. 5 at India's Supreme Court, in the heart of New Delhi. Then white-haired Judge Aftab Alam and his equally dignified, gray-haired colleague Ranjana Desai take their seats. Across from them, an army of lawyers in black robes prepares for the next round in the legal dispute between Novartis, the Swiss pharmaceutical giant, and the Indian state -- and, or course, the domestic pharmaceutical competition.

For the last six years, Novartis has been fighting over a patent for its cancer drug Glivec, appearing before Indian authorities and lower courts. The drug has earned billions for Novartis since it was approved in 2001.

Almost 40 countries, including China and Russia, recognize the company's Swiss patents, but India does not. In defending its position, the Indian Patent Office argues that the drug is not a true novelty, but rather a variation of an existing drug. Non-governmental organizations, such as Medecins Sans Frontieres (MSF, also known as Doctors Without Borders), accuse Novartis of trying to extend its monopoly on Glivec for another 20 years by making minor changes to the drug. The 2005 amendment to the Indian Patents Act outlaws the practice known in professional circles as "evergreening."

Cashing in with Copycat Drugs: For the Supreme Court in India's capital, the case is about more than just one drug and for other multinational pharmaceutical companies, the issue revolves around what they can have patented in India **.**

On the one hand, they are pursuing the goal of capturing the enormous market on the subcontinent, which is growing as the country of 1.2 billion slowly becomes more affluent. On the other hand, India's own pharmaceutical industry is also taking advantage of its Western competitors' patent disputes to go on the offensive with cheaper copycat drugs, or generics.

MSF is already warning that India's role as what it calls the "pharmacy for the poor" will be in jeopardy if Novartis wins its case before the Supreme Court. Indian companies are known for the production of affordable generic drugs that even those in lower socioeconomic groups can afford. In Africa, for example, Indian generics play in important role in fighting the AIDS epidemic. More than 80 percent of all the AIDS patients treated by humanitarian organizations like MSF get their drugs from factories in India.

On this morning, the attorney for Indian drug maker Cipla is using similar arguments to gain the attention of the judges, who he deferentially addresses as "My Lordship" and "My Ladyship," using the language of India's former colonial rulers. At the same time, the Indians are also self-confidently aware of their role as a country that is catching up to the West in industrial terms.

Other Western pharmaceutical giants are also arguing in court to have their patents recognized in the Indian market. The task is as challenging as it is enormous. As the Indian population ages and becomes more affluent, the middle class, in particular, has a growing need for drugs to treat so-called "lifestyle diseases," such as diabetes and heart ailments.

Good for Poor and Profits: The Indian pharmaceutical market is growing by 10 percent a year, and India ranks among the world's top countries in terms of the volume of drugs sold. The management consulting firm PricewaterhouseCoopers predicts that sales will reach $74 billion (€57 billion) by 2020, or five times the sales figure for 2011.

The economic backbone of the subcontinent is made up of not only call centers and software firms, but also of well over 10,000 drug makers. The Indians are capturing the global market with their generics, as they build bases in Europe and the United States or buy stakes in companies there.

In return**,** India is doing its utmost to protect domestic drug companies from foreign competitors. Pharmaceutical giants Pfizer and Roche also recently lost patent suits they had filed in India. And**,** in the spring**,** the Indian Patent Office forced Bayer, the German pharmaceuticals giant**,** to give up its patent for the cancer drug Nexavar**,** thereby paving the way for Natco, an Indian competitor, to produce a generic version.

The Indians invoked the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), under which countries can issue compulsory licenses for drugs if there is a threat of public health emergency caused by things such as epidemics.

This could be characterized as protecting the domestic pharmaceutical industry -- or as expropriating the competition. In any case, the Indian government is using the trick to massively reduce the prices of drugs like Bayer's Nexavar. Someone using the original drug will pay $5,200 per month, while using the Indian generic would only cost $160.

Even that is expensive for Indians, whose average annual per capita income is only $1,514. What's more, there is often a shortage of doctors and hospitals in rural areas, and even in New Delhi, the health care system is unable to handle the crowds of the poor. For example, there are those who wait in long lines for treatment in front of Safdarjang Hospital, the best hospital in the capital. Many are forced to camp out on the dusty roadside under intense heat.

The 'Robin Hood' of the Pharma Industry: Policymakers are partly to blame for these conditions. The Indian state spends less than 2 percent of GDP on its health care system, or far less than other Asian countries. But the current pharmaceutical dispute has less to do with the dire needs of patients than with patents and profits.

Two men -- Yusuf Hamied, the CEO of Cipla, and Ranjit Shahani, the managing director of Novartis India Ltd. -- illustrate the divisions between the two sides.

Both men are Indian, and they live and work only a few blocks away from each other in Mumbai. Nevertheless, they are bitter adversaries from different worlds.

White-haired Hamied, 76, meets with us on the executive floor of Cipla's headquarters. Employees are celebrating a Hindu festival in the courtyard outside, where they have set up a colorful altar to pray for the safety of the machines and the success of the company. But, more than anything, they are excited about dancing.

The music can be heard in Hamied's office. There are black-and-white photographs of his father, the company founder, as he stands next to Mahatma Gandhi, who toured the company in 1935.

The Hamieds were closely aligned with the Indian struggle for independence from the British, and Hamied feels an obligation to uphold this heritage.

He has just come from Germany. First he was in Dresden, where his best friend, classical conductor Zubin Mehta, gave a concert. Then he visited Berlin, a journey that brought back memories of the city where his parents, an Indian Muslim and a Jewish woman from Lithuania, met. In 1935, when the Nazi regime became too threatening for their taste, they left Berlin and returned to Mumbai, where they founded Cipla and where Yusuf grew up.

Since then, the company has grown into a giant, even among India's generic drug manufacturers, with annual sales of about $1.4 billion and more than half of its drugs being sold abroad. Since Hamied challenged the multinational pharmaceutical companies 11 years ago with his own cocktail of AIDS treatment drugs, which he sold at cost, many of his fellow Indians revere him as a sort of Robin Hood of the industry.

In the early 1970s, it was Hamied who convinced then-Prime Minister Indira Gandhi to break the dominance of the multinational pharmaceutical companies in India. She issued strict regulations for foods and drugs that didn't permit patent protections.

Gandhi's decision marked the beginning of a golden age for companies like Cipla because it amounted to a license to copy Western drugs. The prices of important drugs fell by up to 90 percent. But during the course of India's accession to the World Trade Organization (WTO), in 2005, the country agreed to recognize intellectual property, including drug patents.

Hamied is quick to point out that he is also fundamentally in favor of patents. "After all, I'm a chemist myself," he says. Nevertheless, he is pleased that the 2005 law includes Section 3d,

which also plays a role in the legal dispute with Novartis. The passage prohibits "evergreening." For Hamied, patents that are created to maintain existing patent protection by slightly modifying drugs are "frivolous patents."

The Champion of Innovation: Of course, Ranjit Shahani sees things differently, even though he, as a Novartis executive, is clearly playing the more thankless role in his own country. The 65-year-old meets with us in his modest office in a drab concrete building. He began his career with the former British chemical giant ICI before coming to Novartis 15 years ago. Shahani also sees himself as an Indian patriot. He pulls out a brochure depicting smiling people. As part of a program, Novartis provides most Indian patients with Glivec for free.

He is critical of "copycats" like Cipla for ultimately chasing profits for their bosses. He would also say this directly to Hamied, who happens to be a good friend of his. Still, Shahani can't resist maligning his competitor for his luxury penthouse on Regent Street in London and his vineyard in Spain.

Shahani, for his part, says he is worried about India's future. Prime Minister Manmohan Singh's goal of embarking on a "decade of innovation," as he told a group of scientists last year, is an illusion without effective patent protection, says Shahani. Almost with relish, he reports that seven multinational pharmaceutical companies have withdrawn their R&D departments from India in recent years. Since then, members of India's pharmaceutical elite have been conducting their research in Basel or New York.

Shahani also doesn't believe that the 2005 Indian Patents Act guarantees foreign patents in his country. "Even if companies are granted a patent for a drug, it will be infringed," he says. "The only solution is to go to court, but such cases take a long time."

The Hunt for Vulnerable Patents: In the wake of the trials, Indian generic manufacturers, including Natco Pharma, are constantly challenging the multinationals with new products. Natco, with about 2,000 employees, is one of India's smaller companies. But since it received official approval to start producing a generic version of Bayer's Nexavar cancer drug in the spring, Natco has proudly touted itself as the holder of India's first "compulsory license."

The company's drug factory is on the outskirts of Hyderabad, in south-central India. The plant's flat-roofed, utilitarian buildings rise from a rural wasteland of rice fields and stray goats. Inside, however, everything is state-of-the-art. In dust-free rooms, workers wearing masks and special suits sort the tablets coming out of a machine. They earn about 15,000 rupees a month, or roughly €212. Not even the Chinese can compete with wages this low.

The pills are then packaged for export. One is a generic version of the well-known breast cancer drug anastrozole. The logos of various German manufacturers for which Natco works are printed on the packages. Of course, German patients would never suspect that the contents are actually made in India, manager Rami Reddy says with a smile. After all, who would know that the number 164, printed in tiny letters, is the Indian manufacturer's license code?

Natco sees its future in the field of cancer drugs. Its executives in Hyderabad are constantly searching for the drugs of multinationals whose patents are about to expire or have little chance of being recognized in India. Giant markets are waiting in the West, which is why the heads of

India's pharmaceutical companies are relatively nonchalant about the Novartis trial before the Supreme Court.

A few weeks ago, Judge Alam encouraged them when he criticized the price of the cancer drug Glivec, which costs 120,000 rupees a month (€1,700). "Medicine prices are already too high in India," he muttered, and then advised the Novartis attorney to "sell it at five rupees!" If it did that, he added, Novartis could drive out all of its competitors with one blow.

The lawyers for the big drug makers were unimpressed.

Methodology

- When conducting research there are often two research approaches being used namely inductive deduction approach is fundamental based empirical evidences and go as do
- In this doctrinal method of research –The legal propositions by way of analyzing the existing statutory provisions and cases by applying the reasoning and involved the analysis of case law, arranging ordering the systematic legal proposition by rational deduction it help me to focused on preferred value and help to find out the gaps between the policy goal and present state.
- Therefore a research design refers to the entire process of planning and carrying out a deep study which helps me to focus on set issues.
- Research tools are statutes, commentary, books, case study, internet, journals, articles, legal data bases and internet resources etc.
- This research approach will help me to find refined information about the approach of patients, Doctors & NGOs on the prices of Drugs & the reason Behind it
- Personal Interview of Medical Practitioner**,** authorities of hospitals**,** families of those patients suffering from fatal disease & high price of life saving drugs.

References

1. Bouchard Ron.A. **,** Patently Innovative: How Pharmaceutical Firms Use Emerging Patent Law to Extend Monopolioes on Blockbuster Drugs, Cambridge University Press; 1 edition (July 26, 2010).
2. Cornish W.R., Intellectual property right, Ed.2006,sweet and Maxwell, London.
3. Debroy Bibeck**,** Intellectual property right**,** Ed.1998**,** Rajeev Gandhi Foundation**,** New Delhi.
4. Dr. Deere Carolyn ,The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries, Oxford University Press, USA (January 15, 2009).
5. Dr Elizabeth Verkey **,** *The Law of Patents***,** Eastern Book Company,Lucknow, 1st ed.2005.
6. Dr Rimmer Matthew,*Incentives For Global Public Health: Patent Law And Access To Essential Medicines (Connecting International Law With Public Law)*,Cambridge University Press;1st edition (July 26, 2010).
7. Nussbaum. Martha C, *Not For Profit: Why Democracy Needs the Humanities (The Public Square)*, Princeton University Press, First Edition (April 12, 2010).
8. Narayanan P., *Intellectual Property Right*, Eastern Law House Kolkata, 3rd ed.2009.
9. Schere F.M.,*The Patent System and Innovation in Pharmaceutical*, Harvard University press, Cambridge, 2nd ed.1999.

Journals Referred:-

- Basant Rakesh, (1997), `Analysing Technology Strategy Some Issues', Economic and Political Weekly, 32(48), P: M111-120.
- Correa Carlos M., (2000) `Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options', Zed Books Ltd, London and Third World Network, Malaysia.
- Denial kennedy and jems southwick ,2002, TRIPS in the political Economy of international trade law ,Cambridge university press.

- Danzon M Patricia and Chao Wei-Li.., (2000) `Does Regulation Drive Out Competition in Pharmaceutical Markets', The Journal of Law and Economics, 43(2) October.
- Drug Policy 2002: Prescription for Symptoms', (2002a), Economic and Political Weekly, Vol.37, No.30, 3102-3104.
- `Drug Price Control: Who is in Charge? March, (2001),' Economic and Political Weekly, 36(12), P997-998.
- Government of India, (2000), Handbook of Industrial Policy and Statistics, New Delhi.
- Intellectual Property Rights, (IPR) Various Issues, Patent Facilitating Centre, Department of Science and Technology, New Delhi.
- International Intellectual Property Institute, (2000), `Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa', Washington
- Indian Pharmaceutical Industry in the WTO Regime: A SWOT Analysis', (2002b), Economic and Political Weekly, Vol37, No.34, 3542-3555.
- Jensen J.E., (1987), `Research Expenditures and the Discovery of New Drugs', Journal of Industrial Economies, 36(1).
- Lalitha N., (2001), ` Product Patents and Pharmaceutical Industry', a report submitted to the Indian Council of Social Science Research, New Delhi.
- Pradeep Agrawal and P.Saibaba -"TRIPS and Pharmaceutical Industry" Economic and political weekly ,vol.36 no.38 (2001),p 3788.

- Prasad Ashok Chandra and Bhat Shripad (1993), ` Strengthening India's Patent System, Implications for Pharmaceutical Sector' Economic and Political Weekly, 28(21), May, P.1037-105 Rane Wishwas (1995),
- `Drug Prices: Sharp Rise after Decontrol', Economic and Political Weekly, 30(47). November 25, P.2977-2980.
- Report of the Pharmaceutical Research and Development Committee, (1999), Transforming India into a Knowledge Power, Government of India, New Delhi.
- Social Action (1998), `Indian Pharmaceutical Industry: Effects of Proposed Product patent Regime', 48(4), P: 406-431.
- Uruguay Round – Final Act 1994- TRIPS Agreement: Impact of New Patent Regime on Pharmaceuticals, Pesticides and Seeds', in Shiva Vandana (ed) `Biodiversity Conservation Whose Resource? Whose Knowledge?' Indian National Trust for Art and Cultural Heritage, New Delhi.
- `WTO Regime, Host Country Policies and Global Patterns of MNE Activity: Recent Quantitative Studies and India's Strategic Response', _, (2001), Economic and Political Weekly, 36(1), January 39-50.

Websites Referred:-

- http://www.who.org
- http://www.un.org
- http://www.msf
- http://www.epw.org.in
- http://www.eptec.org